UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

TRACY HOWARD, et al., Plaintiffs, v. HAIN CELESTIAL GROUP, INC., Defendant.	Case No. 22-cv-00527-VC **ORDER DENYING MOTION TO DISMISS** Re: Dkt. No. 63

I

Hain Celestial sells food for infants and toddlers under the brand name "Earth's Best." The labels on many of the company's products advertise their nutritional content. Some of these statements are quantitative. For instance, Hain Celestial's Chicken Casserole Puree states "4g PROTEIN per serving" on the front of its label.[1] Other statements are more qualitative. The label on Hain Celestial's Pear Mango Smoothie, for instance, says, "Excellent Source of Calcium, Vitamins C & D." In this lawsuit, the plaintiffs allege that these statements violate a regulation that prohibits manufacturers from making claims about a food's nutrient content on products specifically intended for infants and children under two. They bring a variety of legal claims based on that theory.

In its motion to dismiss the previous iteration of the complaint, Hain Celestial argued in part that its products did not violate the regulation because they were intended for older children.

[1] Hain Celestial asks the Court to take judicial notice of the packaging of the products at issue in this case and several pages from its website. *See* Dkt. No. 64. The request is granted. *See Manchouck v. Mondelez International Inc.*, No. 13-2148, 2013 WL 5400285, at *3 (N.D. Cal. Sept. 26, 2013).

The Court held that based on the totality of the complaint it was plausible to assume the products were intended for those under two. But the Court held that the Food and Drug Administration's regulations allowed Hain Celestial to state that its products were an "excellent source" of different vitamins and minerals, and it dismissed the plaintiffs' claims to the extent that they were based on those "excellent source" statements. *Howard v. Hain Celestial Group., Inc*., No. 22-CV-00527-VC, 2022 WL 11044721, at *2 (N.D. Cal. Oct. 19, 2022).

The plaintiffs then filed an amended complaint, which Hain Celestial has again moved to dismiss. The complaint now alleges that even if the "excellent source" statements are allowed as a general matter, several of Hain Celestial's products do not meet the FDA's standards for what constitutes an excellent source. But the plaintiffs also ask the Court to reconsider its prior decision that the "excellent source" statements are allowed at all.

II

The plaintiffs do not (and could not) sue to directly enforce the FDA's regulations; there is no private right of action allowing them to do so. *See Perez v. Nidek Co*., 711 F.3d 1109, 1119 (9th Cir. 2013). Instead, the plaintiffs bring their claims under state law. But the Nutrition Labeling and Education Act preempts all state law causes of action that impose requirements "not identical to" the requirements imposed by federal law. 21 U.S.C. § 343-1(a)(5); *Hawkins v. Kroger Co*., 906 F.3d 763, 769–70 (9th Cir. 2018). So if the FDA's regulations allow Hain Celestial's "excellent source" statements, then the plaintiffs' claims are preempted. If not, the claims can go forward.

The FDA prohibits most "nutrient content claims" on food "intended specifically" for infants and children under two. 21 C.F.R. § 101.13(b)(3). A "nutrient content claim" is a statement that characterizes the level of a nutrient in a food. 21 C.F.R. § 101.13(b). The FDA is wary of these claims because "many consumers have…limited knowledge" about the quantity of nutrients they should consume every day, so statements "declaring" that a product contains a certain amount of nutrients can be "misleading." 56 Fed. Reg. 60421, 60426 (Nov. 27, 1991). That's all the more true if the food is intended for young children: researchers have given

"relatively little attention" to young children's nutritional needs, *id.* at 60424, and their nutritional needs differ from those of adults.

But there are certain exceptions to this general prohibition. Of importance here, the regulations allow manufacturers of such food to "describe[] the percentage of a vitamin or mineral in the food" in relation to the reference daily intake for that vitamin or mineral (unless the FDA determines the specific statement is otherwise misleading). 21 C.F.R. § 101.13(q)(3)(i). "Reference daily intake," or RDI, refers to the amount of a vitamin or mineral that the FDA recommends for daily consumption.[2] The FDA has established different reference daily intakes for different groups, including infants, children aged one to three, and people over four. *See* 21 C.F.R. § 101.9(c)(8)(iv). Most labels do not explicitly reference RDI. Instead, they refer to the "% daily value" of a food. That "% daily value" is calculated by dividing the amount of the vitamin or mineral by the reference daily intake for that vitamin or mineral. 21 C.F.R. § 101.9(c)(8)(i). If a food is intended for young children, the manufacturer must calculate the percent based on the reference daily intake established for the intended consumer's specific age group. *Id.*

This exception for percentage statements seems consistent with the FDA's general approach to nutrient content claims. If consumers don't know how much of a vitamin or mineral a young child should consume every day, then a statement about the amount of that vitamin or mineral in a product might be misleading. But these percentage statements give the consumer more context; they show the consumer how the food fits into a child's daily nutritional needs.

The question in this case is whether the "excellent source" statements "describe the percentage of a vitamin or mineral" within the meaning of the regulation. In its prior ruling, the Court thought the answer was yes. *Hain Celestial Group*, 2022 WL 11044721, at *2; *see also Bruton v. Gerber Prod. Co.*, 961 F. Supp. 2d 1062, 1093–94 (N.D. Cal. 2013), *rev'd and remanded on other grounds*, 703 F. App'x 468 (9th Cir. 2017) (holding the same). The reason

[2] The term "reference daily intake" refers to the recommendations for vitamins and minerals specifically. For macronutrients, the FDA generally refers to these recommendations as "daily reference values." *See* 21 C.F.R. § 101.9(c)(8)(iv); 21 C.F.R. § 101.9(c)(9); *Ackerman v. Coca-Cola Co.*, No. CV-09-0395 (JG), 2010 WL 2925955, at *9 n.15 (E.D.N.Y. July 21, 2010).

was that, elsewhere in its regulations, the FDA provides that the phrase "excellent source" may be used if the "food contains 20 percent or more of the [reference daily intake]…per reference amount customarily consumed." 21 C.F.R. § 101.54(b)(1).[3] Under the regulations, then, to say something is an "excellent source" of a vitamin or mineral is to say that it has 20% or more of the reference daily intake for that vitamin or mineral. Such a statement does, indirectly and in a colloquial sense, "describe" the percentage of a vitamin or a mineral in relation to the reference daily intake.

But the Court's prior ruling was wrong as a legal matter. Based on the text of the regulations and their authorizing statute, the history of the regulations authorizing "excellent source" statements in particular, and the FDA's own guidance, the "excellent source" statements should not be understood to "describe" the percentage of a vitamin or mineral within the meaning of the regulation.

Beginning with the text, the FDA's regulations—and the statute they are based on—make a subtle distinction between statements that "characterize" the percentage of a vitamin or mineral and statements that "describe" that percentage. The "describing" statements are a subset of the "characterizing" statements. (And only the "describing" statements are allowed on food specifically intended for infants and children under two.)

The Nutrition Labeling and Education Act, the statute the FDA relied on in adopting these regulations, establishes the distinction. *See* 58 Fed. Reg. 33731, 33739 (June 18, 1993) (citing the statute as the reason for the regulation). Broadly speaking, section 343 of the Act "establish[es] the conditions under which food is considered 'misbranded.'" *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1116 (N.D. Cal. 2010). Subsection (r) addresses nutrition claims made outside of a label's nutrition facts panel (the black-and-white box that lists a product's nutrition facts and ingredients). That subsection first recognizes a broad category of statements that "characterize" the level of a nutrient. *See* 21 U.S.C. § 343(r)(1)(A). The FDA's

[3] There are some nuances to this regulation that are not relevant here. *See* 21 C.F.R. § 101.54(b)(2) (regulating "excellent source" statements on meal products and main dish products).

regulations refer to these statements as "nutrient content claims." 21 C.F.R. § 101.13(b). To make a nutrient content claim, a manufacturer must comply with the requirements listed in subsection (r)(2)(A) of the Act. 21 U.S.C. § 343(r)(2)(A). Among other requirements, the manufacturer can only "use[] terms" that the FDA has defined in its regulations. § 343(r)(2)(A)(i). That means that, for the general set of nutrient content claims, the language a manufacturer can use is limited by regulation.

But subsection (r)(2)(E) carves an out an exception to many of these requirements for a subset of nutrient content claims, statements that "describe[] the percentage of vitamins and minerals" in relation to the amount recommended for daily consumption. § 343(r)(2)(E). Manufacturers can make these statements even if the FDA has not specifically defined the terms that a manufacturer must use when making them.

There's only one interpretation of the Act that harmonizes these provisions: to "describe" the percentage of a vitamin or mineral, the statement must be explicitly quantitative and involve a specific percentage, something like "28% of the reference daily intake for vitamin C."[4] More qualitative statements, like "excellent source of vitamin C," do not "describe" the percentage of a vitamin or mineral within the meaning of the Act (or its regulations).

It's significant that subsection (r)(2)(E) refers to these statements as "describing," rather than "characterizing" the percentage. It's a "well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words." *S.E.C. v. McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003). And it's clear from the structure of the Act that "characterize" must have a more capacious definition than "describe." So, there must be some category of statements that "characterize" the percentage of a vitamin or mineral—without describing that percentage. It's difficult to imagine any statement that would fall into that category if the "excellent source" statements do not.

[4] As noted, most labels do not actually refer to reference daily intake; they refer to the % daily value, which is calculated using the reference daily intake. In practice, a manufacturer would probably say "28%DV of Vitamin C" here, and that would seem to be consistent with the regulations. This ruling uses "reference daily intake" in this example for the sake of simplicity.

This interpretation is further supported by the requirements imposed for the different kinds of statements. As noted, a manufacturer can "describe" the percentage of a vitamin or mineral even if the FDA has not defined the terms the manufacturer must use when doing so. That makes sense for explicitly quantitative statements of percentage like "28% of the reference daily intake for vitamin C." These statements are relatively straightforward, so manufacturers can make them without more specific authorizing regulations.

But qualitative statements—statements like "excellent source of vitamin C"—are more subjective. Without a standard definition, the term "excellent source" could mean a variety of things. It could mean that the food has 10% or 20% or 30% of the recommended amount of a vitamin or mineral. Or it could mean something else entirely. So, the Act says manufacturers can only make these statements if the FDA had defined (and therefore standardized) the terms these manufacturers can use.

This interpretation is also consistent with the history of the regulations authorizing "excellent source" statements. The phrase "excellent source" is a synonym for "high": When a manufacturer says something is an "excellent source of vitamin C," that's the same thing as saying it's "high in vitamin C." 21 C.F.R. § 101.54(b)(1). Either statement means that the food has some percentage greater than 20 percent of the amount of vitamin C recommended for daily consumption. And the Act required the FDA to define the term "high" under the authority given in (r)(2)(A), the general provision that applies to nutrient content claims. *See* Nutrition Labeling & Education Act, Pub. L. 101-535, § 3(b)(1)(A)(iii), 104 Stat. 2353, 2361 (1990). In passing the Act, then, Congress understood that the general requirements for nutrient content claims—including the requirement that the FDA define their terms—would apply to "high" statements. That suggests "high" statements "characterize" the level of a nutrient but do not "describe" the percentage of a vitamin or mineral—and the same must be true of synonymous "excellent source" statements.

Finally, this conclusion is confirmed by the FDA's own interpretation of the Act and its regulations. According to various FDA warning letters, "excellent source" statements are not allowed on products specifically intended for infants and children under two. *See* Dkt. No. 58 at

64–68. Even if these letters are not entitled to deference, they offer some additional support for this view. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2414 (2019).

III

The upshot of all this is that the plaintiffs have plausibly alleged that Hain Celestial's "excellent source" statements violate the FDA's regulations, and so the plaintiffs' claims are not preempted. While the FDA allows manufacturers to make statements that "describe" the percentage of a vitamin or mineral on food specifically intended for infants and children under two, the "excellent source" statements do not fall into that category. The motion to dismiss is therefore denied.[5]

IT IS SO ORDERED.

Dated: February 13, 2023

VINCE CHHABRIA
United States District Judge

[5] Because the FDA has not authorized the "excellent source" statements, the Court need not reach the question of whether Hain Celestial's products meet the FDA's requirements for what constitutes an excellent source.